## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Werner *et al.* Confirmation No.: 1581 Appl No.: 10/559,430 Group Art Unit: 1638

Filed: January 17, 2006 Examiner: Fox, David T.

For: SAFE PRODUCTION OF A PRODUCT OF INTEREST IN HYBRID SEEDS

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## RESPONSE TO RESTRICTION REQUIREMENT

This is in response to the Office Action dated March 19, 2008, in which the Examiner has required restriction between Group I, namely Claims 1-8 (in part), 9-13, 18-19 (in part), 20, 30-34 (in part), and 36 (in part), Group II, namely Claims 1-8 (in part), 14-17, 18-19 (in part), 21-23, 30-34 (in part), and 36 (in part), Group III, namely Claims 1-8 (in part), 24, 27-29, 30-34 (in part), and 36-37 (in part), Group IV, namely Claims 14 (in part), 25-26, 30-34 (in part), and 36-37 and Group V, namely Claim 35. If Applicants elect Group III, the Examiner further requires the election of a single species from:

Species A. Replicating DNA molecules, Claims 1-8, 24, 27-29, 30-34, and 36-37; and Species B. Replicating RNA molecules, Claims 1-8, 24, 27-29, 30-34, and 36-37.

Applicants hereby provisionally elect with traverse to prosecute the claims of Group I (Claims 1-8 (in part), 9-13, 18-19 (in part), 20, 30-34 (in part), and 36 (in part)) and expressly reserve the right to file divisional applications or take such other appropriate measures deemed necessary to protect the inventions in the remaining claims.

Applicants, however, respectfully disagree with the Restriction Requirement because the application, in contrast to the position stated the Office Action, does not lack unity of invention for the reasons set forth below. Therefore, Applicants respectfully request that the Examiner reconsider the requirement for restriction and examine all of the claims together in the present application.

The Office Action asserts that the inventions of Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, the inventions of Groups I-V lack the same or corresponding technical features. The Office Action states on page 4 that the inventions of Groups I-V "are linked by the technical feature of a method of hybridizing a first and

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second transgenic plant, each containing only one genetic endowment, wherein the seed or seedling produced by said hybridization produces the desired product, and wherein the desired product is isolated from the seed or seedling." The Office Action then asserts "this feature is not special because it does not produce an advance over the prior art," citing EP 1 048 734. The Office Action indicates that EP 1 048 734 teach the hybridization of two plants—one containing a genetic endowment encoding a heavy chain of an immunoglobulin and the other containing a genetic endowment encoding a light chain—to produce progeny seeds and plants which produce a multimeric protein immunoglobulin protein that may be isolated from the progeny plants.

In contrast to the view of the Office Action, the present invention is an advance over the prior art. EP 1 048 734 merely mentions isolating a population of progeny (see, paragraph 35 on page 8). Thus, the progeny population of EP 1 048 734 is not destroyed but may reach the reproductive stage, whereby the biological safety achievable in the present invention is not achieved in EP 1 048 734. Furthermore, the Applicants have stated advantages that their invention has over the prior art, including EP 1 048 734, in the paragraph that bridges pages 4 and 5 of their specification:

The inventors of the invention have found a process of producing a product of interest in plant seeds (F1 seeds). The genetic endowment required for said process is generated in said seeds by hybridizing parent plants, i. e. none of the parent plants has the complete genetic endowment required for said process. The seeds wherein the product of interest is produced are destroyed when said product is isolated therefrom. Consequently, the process of the invention is of high biological safety, as the genetic endowment required for said process has a very low probability of being distributed in the environment. Additionally, said F1 seeds may be sterile for further improving biological safety, since a plant grown from said seed cannot reproduce. Further, the process of the invention has the surprising advantage that gene silencing is not a problem for the production of said product of interest. This may be due to the short coexistance of the partial genetic endowments of the parental plants in said seeds. Notably, since production of said product of interest does basically not occur in the parental plants, no transgene silencing can be transmitted to said seeds. As transgene silencing hardly occurs, said product of interest can be produced in high yield. It is a further advantage of the invention that plant growth and isolation of the product of interest can be separated in space and time, since the product of interest is usually more stable in seeds than in other plant tissues. This adds flexibility to the overall process of the invention.

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Accordingly, Applicants, invention is an advance over EP 1 048 734. Therefore, the finding that the present application lacks unity of invention is not properly supported by the cited document and should be withdrawn.

For the above reasons, Applicants submit that the Restriction Requirement is improper and should be withdrawn because the present application relates to a single general inventive concept under PCT Rule 13.1 and therefore, satisfies the requirement of unity of invention. Accordingly, Applicants respectfully request that the Examiner examine all of the claims together in the instant application.

Should the Examiner have further questions or comments with respect to examination of this case, it is respectfully requested that the Examiner telephone the undersigned so that further examination of this application can be expedited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those, which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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ELECTRONICALLY FILED USING THE EFS-WEB ELECTRONIC FILING SYSTEM OF THE UNITED STATES PATENT & TRADEMARK OFFICE ON April 30, 2008.